

REMARKS

I. Status of the Application

Claims 1-7, 10, 11, 13-17, 19 and 21-26 are presently pending in the application. Claims 1-7, 13-17, 19 and 21-26 stand rejected under 35 U.S.C. § 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over, Mahmood et al., U.S. Patent No. 6,656,489. Claims 1-7, 10, 11, 13-27, 19 and 21-26 stand rejected under 35 U.S.C. § 103(a) as being obvious over Mahmood et al. and Goedemoed, EP 0 830 859 A2. Claims 1-7, 10, 13-17, 19 and 21-26 stand rejected under 35 U.S.C. § 103(a) as obvious over Bakker et al., U.S. Patent Appl. Publ. No. 2002/0095213, in view of Steinke et al., U.S. Patent Appl. Publ. No. 2003/0199969, Wallace et al., U.S. Patent No. 6,280,457, and Tormala et al., U.S. Patent Appl. Publ. No. 2003. Claims 1-7, 10, 11, 13-17, 19 and 21-26 stand rejected under 35 U.S.C. § 103(a) as being obvious over Bakker et al., in view of Steinke et al., Wallace et al., and Tormala et al., further in view of Goedemoed et al.

Applicants have amended the specification to include the headings “BACKGROUND,” “SUMMARY,” “BRIEF DESCRIPTION OF THE DRAWINGS” and “DETAILED DESCRIPTION OF CERTAIN PREFERRED EMBODIMENTS.” The specification was further amended to include text describing the figures, support for which can be found at least at Figures 1 and 2 as originally filed.

The amendments presented herein add no new matter. Applicants respectfully request entry and consideration of the foregoing amendments and reconsideration of the application in view of the following remarks, which are intended to place this case in condition for allowance.

II. Formal Matters

At page 2 of the instant Office Action, the specification is objected to because the Brief Description of the Drawings is missing. In response, Applicants have amended the specification to include this section. Accordingly, Applicants respectfully request that this objection be withdrawn.

III. Claims 1-7, 13-17, 19 and 21-26 Are Novel and Nonobvious over Mahmood et al.

At page 2 of the instant Office Action, claims 1-7, 13-17, 19 and 21-26 stand rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Mahmood et al., U.S. Patent No. 6,656,489. The Office Action states that Mahmood et al. teach a scaffold for tissue engineering cartilage comprising a layer of ceramic and a layer of PEG/PBT copolyester having bioactive agents. Applicants respectfully traverse this rejection.

The pending claims are directed in part to medical device having a surface and a coating applied to the surface. The claimed *surface* includes a material selected from the group consisting of *metals, metal alloys, ceramics, and glasses*. The claimed *coating, which is applied to the surface of the medical device*, includes a *copolymer* of a polyalkylene glycol terephthalate, an aromatic polyester and a biologically active agent. Thus, Applicants' claimed medical device has a *surface that is coated with a copolymer*. Applicants' claimed medical device advantageously overcomes deficiencies suffered by medical devices known in the art at the time of filing of the instant application. In particular, Applicants' claimed medical device provides a copolymer coating that is capable of undergoing deformation *in vivo* without breaking or coming loose (paragraphs [0005] and [0007] of the published application). This prevents

exposure of the underlying surface to surrounding tissue *in vivo*, as well as prevents pieces of the coating from dissociating from the surface completely. *Id.* Further, Applicants' claimed medical device includes a biologically active agent that can provide therapeutic and/or prophylactic properties when implanted.

Mahmood et al. fails to teach or suggest the claimed invention. First of all, Mahmood et al. teaches tissue engineering scaffolds made of a ***copolymer matrix coated with ceramic*** (title, abstract). Thus, the copolymer is on the inside (the matrix) and the ceramic is on the outside. In contrast, Applicants' claimed medical device has a metal, metal alloy, ceramic or glass ***surface*** that is ***coated with a copolymer***. Thus, the physical arrangement of the scaffolds of Mahmood et al. is very different from the physical arrangement of Applicants' claimed medical implants. Simply because Mahmood et al. discloses scaffolds having ceramic and a copolymer does not mean that this reference teaches or suggests Applicants' claimed invention.

The physical arrangement of Applicants' medical device is critical to its success when used *in vivo*. As discussed above, Applicants' claimed surface/coating arrangement provides an implant having an elastic surface that can be deformed *in vivo* without damaging its physical integrity. Mahmood et al. does not teach or suggest a medical implant having a surface coated with a copolymer. Instead, the scaffolds of Mahmood et al. have a ***ceramic coating*** which could readily crack or crumble upon deformation of the underlying copolymer matrix.

Further, there is no teaching or suggestion by Mahmood et al. to flip their scaffolds inside out such to arrive at a ceramic scaffold that is coated by a copolymer, or that such an implant would be desirable. In fact, Mahmood et al. teaches that it is ***desirable*** to have a ***ceramic coating***: "It has been found that the presence of a ***ceramic coating*** is ***highly beneficial***," (column 5, lines 7-8, emphasis added).

Finally, Mahmood et al. fails to teach or suggest the inclusion of a biologically active agent in their coating, as required by the claimed invention. Instead, Mahmood et al. teaches that bioactive agents may be added to the inner scaffold (abstract; column 4 line 64 to column 65, line 3). Nowhere does Mahmood et al. teach or suggest adding a bioactive agent to their ceramic coating.

For at least these reasons, Mahmood et al. fails to teach or suggest or suggest Applicants' claimed medical devices. Accordingly, Applicants respectfully request that the rejection of claims 1-7, 13-17, 19 and 21-26 under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Mahmood et al. be reconsidered and withdrawn.

IV. Claims 1-7, 10, 11, 13-17, 19 and 21-26 Are Nonobvious over Mahmood et al. in view of Goedemoed et al.

At page 2, of the instant Office Action, claims 1-7, 10, 11, 13-17, 19 and 21-26 stand rejected under 35 U.S.C. § 103(a), as obvious over Mahmood et al. in view of Goedemoed et al., EP 0 830 859 A2. The Office Action states that the instant invention further recites particular biologically active agents such as proteins over Mahmood et al., but that those proteins are well known in the art as taught by Goedemoed et al. The Office Action concludes that it would have been obvious to one skilled in the art at the time of the invention to utilize the biologically active agents of Goedemoed et al. in the copolyester coating composition of Mahmood et al. since Mahmood et al. teach employing biologically active agents. Applicants respectfully traverse this rejection.

For at least the reasons set forth above, Applicants respectfully submit that Mahmood et al. fails to teach or suggest the claimed invention. Further, Applicants respectfully disagree with the Office Action's assertion that Mahmood et al. teaches or suggests a copolymer *coating*

composition. Mahmood et al. teaches that the *matrix* is made of a *copolymer* and that this matrix may be *coated with ceramic*, not a copolymer coating.

Goedemoed et al. fails to cure the deficiencies of Mahmood et al. Goedemoed et al is directed to pharmaceutical compositions which include a biologically active agent encapsulated in a *copolymer matrix* (page 2, lines 1-6). The pharmaceutical compositions of Goedemoed et al. may be microspheres, discs, rods, pellets, films, sheets or threads (page 7, lines 19-22, examples). Nowhere does Goedemoed et al. teach or suggest a medical device comprising a surface of metal, metal alloy, ceramic or glass in which a copolymer coating is applied to the surface of the medical device, as required by the claimed invention, or that such a device would be desirable.

Thus, the combination of Mahmood et al. and Goedemoed et al. fails to teach or suggest the claimed invention. Accordingly, Applicants respectfully request that the rejection of claims 1-7, 10, 11, 13-17, 19 and 21-26 under 35 U.S.C. § 103(a), as obvious over Mahmood et al. in view of Goedemoed et al. be reconsidered and withdrawn.

V. **Claims 1-7, 10, 13-17, 19 and 21-26 Are Nonobvious over Bakker et al., in view of Steinke et al., Wallace et al., and Tormala et al.**

At page 3 of the instant Office Action, claims 1-7, 10-11, 13-17, 19 and 21-26 stand rejected under 35 U.S.C. § 103(a) as being obvious over Bakker et al., U.S. Pat. Pub. No. 2002/0095213, in view of Steinke et al., U.S. Pat. Pub. No. 2003/0199969, Wallace et al., U.S. Patent No. 6,280,457, and Tormala et al., U.S. Pat. Pub. No. 2003/0206928. The Office Action states that Bakker et al. teach polymeric medical devices coated with the instant copolymer of PEGT and PBT. The Office Action concludes that it would have been obvious to one skilled in the art at the time of the invention to utilize the well-known biologically active agent of Wallace

et al. in the polyester coating composition of Bakker et al., and to coat medical devices made of the instant metals, metal alloys or ceramics taught by Steinke et al. and Wallace et al. since medical devices made of the instant metals, metal alloys and ceramics are well-known in the art and since coating of a medical device with a polymeric coating composition containing biologically active agents in order to prevent infections or improve cell growth is a routine practice in the art as taught by Wallace et al. and since Bakker et al. teach coating medical devices with the polyester.

Applicants respectfully traverse this rejection. The combination of references cited in the Office Action fails to render the claimed invention obvious. Applicants respectfully submit that the mere fact that references can be combined does not render the resultant combination obvious unless the prior art also *suggests the desirability of the combination*. Furthermore, one of skill in the art would need to understand that the modification to arrive at the claimed subject matter can be made with a *reasonable expectation of success*.

Applicants' claimed invention is directed in part to a medical device comprising a surface and a *coating* applied to the surface of the medical device, in which the coating includes a copolymer of a polyalkylene glycol terephthalate and an aromatic polyester and a biologically active agent, and the surface is a metal, metal alloy, ceramic or glass. Applicants' claimed coating provides a solution to the art-recognized problem concerning coating materials that are insufficiently adhered to the surface of a medical device. Applicants respectfully submit that the combination of references cited in the instant Office Action fails to render Applicants' claimed implant obvious.

Bakker et al. is directed to prosthetic devices comprised of a polymer having calcium deposited thereon or therein (paragraph [0002]). Bakker et al. teaches that their implants may

contain soft polymers and hard polymers (paragraphs [0009], [0010], [0016] – [0018]). Nowhere does Bakker et al. teach or suggest *coating* a metal, metal alloy, ceramic or glass with the claimed copolymer. Further, one of skill in the art, based on the teachings of Bakker et al. would find no motivation to do so, particularly given the fact that Bakker et al. teaches the *unsuitability* of glasses and ceramics due to their lack of elasticity (paragraph [0070]). In fact, when Bakker et al. teaches that a glass or ceramic can be used, it is admixed as a *filler material* (paragraph [0094]), not as the surface of a medical device, as claimed by Applicants. In addition, nowhere in Bakker et al. would one of skill in the art find any teaching to suggest that the claimed copolymer could *effectively* be attached to the surface of the claimed medical device with a reasonable expectation of success. Finally, Bakker et al. fails to teach or suggest adding a biologically active agent to Applicants' claimed copolymer coating. Accordingly, Bakker et al. fails to teach or suggest the claimed invention.

Steinke et al. fails to cure the deficiencies of Bakker et al. Steinke et al. is directed to expandable intraluminal stents that may be made from preferred materials including stainless steel, tantalum, titanium, tungsten, gold, platinum, iridium, rhodium and alloys thereof (paragraph [0013] and [0080]). Although Steinke et al. teaches that stents may be partially made from a degradable polymeric material (paragraph [0082]), nowhere does Steinke et al. teach or suggest *coating* their stents with the claimed copolymer. Based on the teachings of Steinke et al., one of skill in the art would find no motivation to coat a medical device comprising the claimed materials with the claimed copolymer, nor would they conclude that such a device could be made with a reasonable expectation of success.

Wallace et al. fails to cure the deficiencies of Bakker et al. and Steinke et al. Wallace et al. is directed to vaso-occlusive devices that are merely *wrapped* with a polymeric *fiber* (column

2, lines 62-67), not coated, as claimed by Applicants. Wallace et al. teaches that their polymeric fibers have a *monofilament or a multifilament* construction in which a plurality of single filaments are wound, braided or otherwise joined together (column 3, lines 1-4). Thus, Wallace et al. teaches *winding* a polymeric fiber *around* their device, *not coating* it with the claimed copolymer. Wallace et al. next teaches, “[o]bviously, the polymeric fiber is *first placed on the wire* per se and the *combination of fiber and wire* is *then made into the secondary shape, i.e., the helical coil*” (column 5, lines 61-64, emphasis added). Given this teaching by Wallace et al. that the polymer is *necessarily* wrapped around the underlying wire *prior* to coiling into a helical coil, one of skill in the art would not be motivated to coat the wire with the claimed polymer with a reasonable expectation of success at least because the coating would likely crack and break apart from the wire during the radical structural changes that would occur when forming the wire into the desired helical coil shape. Indeed, nowhere does Wallace et al. teach that their polymeric fiber would have good adherence to their implants.

Tormala et al. fails to cure the deficiencies of Bakker et al., Steinke et al. and Wallace et al. Tormala et al. is directed to composites and devices including a matrix of a bioabsorbable polymer or copolymer and bioactive ceramic or glass particles *dispersed in the polymer matrix* (paragraph [0012]). Nowhere does Tormala et al. teach or suggest the desirability of coating the surfaces of their devices with any copolymer, let alone coating the surface of a medical device with the copolymer claimed by Applicants with a reasonable expectation of success.

A *prima facie* case of obviousness cannot be made because the references fail to provide motivation to combine and modify their teachings to arrive at the claimed subject matter with a reasonable expectation of success. Accordingly, Applicants respectfully request that the rejection of claims 1-7, 10-11, 13-17, 19 and 21-26 under 35 U.S.C. § 103(a) as being obvious

over Bakker et al. in view of Steinke et al., Wallace et al. and Tormala et al. be reconsidered and withdrawn.

VI. Claims 1-7, 10, 11, 13-17, 19 and 21-26 Are Nonobvious over Bakker et al., in view of Steinke et al., Wallace et al., and Tormala et al., Further in view of Goedemoed et al.

At page 4 of the instant Office Action, claims 1-7, 10, 11, 13-17, 19 and 21-26 stand rejected under 35 U.S.C. § 103(a) as being obvious over Bakker et al., in view of Steinke et al., Wallace et al., and Tormala et al., further in view of Goedemoed et al. The Office Action states that it would have been obvious to one skilled in the art at the time of the invention to utilize the biologically active agents of Goedemoed et al. in the copolyester coating composition of Bakker et al. in coating the medical devices of Steinke et al., Wallace et al. and Tormala et al. since Wallace et al. teach the use of biologically active agents. Applicants respectfully traverse the rejection.

As discussed above, the primary references fail to render the claimed invention obvious. Goedemoed et al. fails to cure the deficiencies of these references. As discussed in section IV, nowhere does Goedemoed et al., which is directed to copolymer matrices, teach or suggest a medical device comprising metal, metal alloy, ceramic or glass, in which a copolymer coating is applied to the surface of the medical device, as required by the claimed invention. Nor would one of skill in the art conclude, based on the teachings of Goedemoed et al., that such a device could be made with a reasonable expectation of success.

Thus, this combination of references fails to motivate one of skill in the art to arrive at the claimed subject matter with a reasonable expectation of success. Accordingly, Applicants respectfully request that the rejection of claims 1-7, 10, 11, 13-17, 19 and 21-26 under 35 U.S.C.

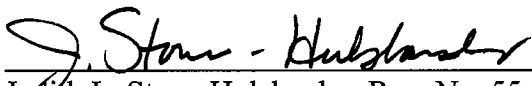
§ 103(a) as being obvious over Bakker et al. in view of Steinke et al., Wallace et al. and Tormala et al., further in view of Goedemoed et al., be reconsidered and withdrawn.

VII. Conclusion

Having addressed all outstanding issues, Applicants respectfully request entry and consideration of the foregoing amendments and reconsideration and allowance of the case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone Applicants' attorney at the number below.

Respectfully submitted,

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